VIRGINIA PAXLOVID EMERGENCY USE CHECKLIST

Last Updated: 1.25.22

This form is to be completed by the prescribing provider to assist in determining patient eligibility for paxlovid (nirmatrelvir/ritonavir). This checklist is based on currently available evidence, resources, information, emergency use authorization and expert opinion and is subject to change.

Prescribing Provider Name: _____ Date and time of prescription: _____
Patient name: _____ Patient Date of Birth: _____

REQUIRED TESTING PRIOR TO ADMINISTRATION

- COVID-19 RT-PCR or antigen test
- Vital Signs, including weight in kilograms (kg), and Pulse Oximetry

INCLUSION CRITERIA

All must be included to be compliant with EUA.

- COVID-19 Positive via PCR or antigen, positive test date: _____
- Patient is 12 years of age or older
- Patient is at high-risk for the progression of COVID-19 to severe illness
- Time since symptom onset, **less than 5 days**. Approximate **symptom onset date**: _____
    - Please circle patient's symptoms:
        - Cough
        - Shortness of breath or difficulty breathing
        - Fever
        - Chills
        - Muscle pain
        - Sore throat
        - GI symptoms
        - Diarrhea
        - Other_____
- Does the patient have mild to moderate disease?: Yes / No
- Patient weight in kg (must weigh 40kg or more): _____

EXCLUSION CRITERIA

Any below are contrary to authorized use.

- Patient under age 12
- Patient weighs less than 40kg
- eGFR < 30 mL/min/1.73m2 or patient on hemodialysis or hemofiltration
- Severe hepatic impairment (Child-Pugh Class C)
- Known hypersensitivity to any ingredient of Paxlovid (nirmatrelvir or ritonavir)
- Contraindicated in patients taking the following drugs:
    - Alpha1-adrenoreceptor antagonist: alfuzosin
    - Analgesics: pethidine, piroxicam, propoxyphene
    - Antianginal: ranolazine

- Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine
- Anti-gout: colchicine
- Antipsychotics: lurasidone, pimozide, clozapine
- Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine
- HMG-CoA reductase inhibitors: lovastatin, simvastatin
- PDE5 inhibitor: sildenafil (Revatio®) when used for pulmonary arterial hypertension
- Sedative/hypnotics: triazolam, oral midazolam
- Paxlovid cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer:
    - *o* Anticancer drugs: apalutamide
    - *o* Anticonvulsant: carbamazepine, phenobarbital, phenytoin
    - *o* Antimycobacterials: rifampin
    - *o* Herbal products: St. John's Wort (hypericum perforatum)
- These interactions may lead to clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications.
- See Table 1 in the linked fact sheet for additional clinically significant drug interactions that should be considered prior to prescribing nirmatrelvir/ritonavir (https://www.covid19oralrx-hcp.com/files/Fact_Sheet_HCP.pdf)

NIRMATRELVIR/RITONAVIR DOSING AND COUNSELING

- Patient age 12 years or older AND weight greater than or equal to 40 kg AND eGFR ≥60 mL/min: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together orally twice daily for 5 days. Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID
- Dose reduction for moderate renal impairment: Patient 12 years or older AND weight greater than or equal to 40 kg AND eGFR ≥ 30 to < 60 mL/min: 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days
- Note: Not authorized for use for longer than 5 consecutive days

It **MUST be documented in the patient's medical record prior to prescribing** nirmatrelvir/ritonavir that **informed consent** process took place, in which the risks, benefits, unknowns of the proposed treatment, and reasonable treatment alternatives were discussed with patient/surrogate and their acceptance or refusal documented and the **patient/surrogate has been provided the following**:

- The Fact Sheet for Patients and Parents/Caregivers: https://www.covid19oralrx-hcp.com/files/Fact_Sheet_Patient.pdf
- Informed of alternatives to receiving nirmatrelvir/ritonavir
- Informed that nirmatrelvir/ritonavir is an unapproved drug authorized for use under FDA EUA

If a serious and unexpected adverse event occurs and appears to be associated with the use of nirmatrelvir/ritonavir, the prescribing health care provider and/or the provider's designee shall complete and submit a MedWatch form to FDA using one of the following methods:

- Complete and submit the report online: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting, or
- Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or

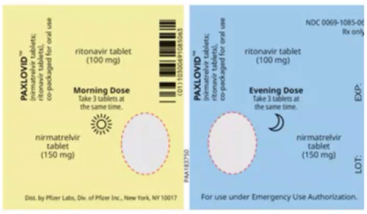
- Call 1-800-FDA-1088 to request a reporting form

CONDITIONS OF AUTHORIZATION FOR THE USE OF NIRMATRELVIR/RITONAVIR FROM THE STATE OF VIRGINIA

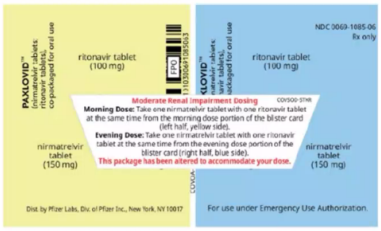
- You attest that all information in this form is true to the best of your ability
- You may contact the pharmacy to verify they have supply and send them the copy of the COVID-19 positive test result
- You agree to complete and submit a MedWatch form for all adverse reactions and serious adverse or unexpected adverse events that are considered potentially attributable to molnupiravir as directed by the EUA issued by the FDA for nirmatrelvir/ritonavir within 7 calendar days from the onset of event (refer to EUA for reportable events)
- You may submit all serious adverse events and all medication errors to the State of VA by reporting the event(s) to the Virginia Poison Center at (800) 222-1222 as soon as possible but no later than three days after time of error or adverse reaction

INSTRUCTIONS FOR DISPENSING FOR RENAL ADJUSTMENT INSTRUCTIONS:

STEP 1: *remove one 150mg nirmatrelvir tablet from each dose of the blister card (closest to middle)*

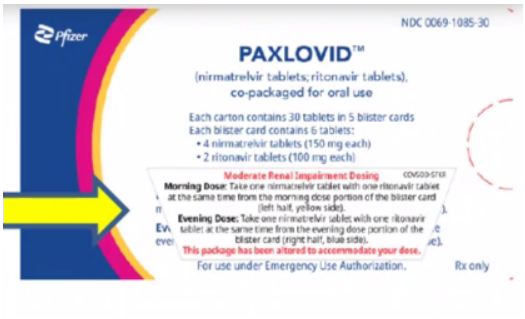


STEP 2: *affix blister card with one sticker from the provided tear pad to cover the blister cavities*



STEP 3: *repeat steps 1 and 2 for every blister card in the carton (total of 5)*

STEP 4: *affix one sticker from provided tear pad to cover the pre-printed dosing regimen on carton (new dosing regimen for renal adjustment)*


Pfizer
NDC 0069-1085-30
PAXLOVID™
(nirmatrelvir tablets; ritonavir tablets),
co-packaged for oral use
Each carton contains 30 tablets in 5 blister cards
Each blister card contains 6 tablets:
• 4 nirmatrelvir tablets (150 mg each)
• 2 ritonavir tablets (100 mg each)
Moderate Renal Impairment Dosing
COVID-0768
Morning Dose: Take one nirmatrelvir tablet with one ritonavir tablet
at the same time from the morning dose portion of the blister card
(left half, yellow side).
Evening Dose: Take one nirmatrelvir tablet with one ritonavir
tablet at the same time from the evening dose portion of the
blister card (right half, blue side).
This package has been altered to accommodate your dose.
For use under Emergency Use Authorization.
Rx only